

#17

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|   |   |    |                          |                        |          |
|---|---|----|--------------------------|------------------------|----------|
| Substitute for form 1449A/PTO   |   |    | <b>Complete if Known</b> |                        |          |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    | Application Number       | 09/639,289             |          |
|   |   |    | Filing Date              | 08/15/2000             |          |
|   |   |    | First Named Inventor     | M. Dedhiya             |          |
|   |   |    | Art Unit                 | 1619                   |          |
|   |   |    | Examiner Name            | L. Wells               |          |
| Sheet   | 1 | of | 1                        | Attorney Docket Number | 01895284 |

| U.S. PATENT DOCUMENTS |                       |  |                                |  |   |
|-----------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials*    | Cite No. <sup>1</sup> | Document Number                            | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       |                       | Number - Kind Code <sup>2</sup> (if known) |                                |  |   |
| XQW                   | 1                     | us-5939429                                 | 08/17/1999                     | Kunos, et al.                                      |   |
|                       | 2                     | us-5922306                                 | 07/13/1999                     | Akehurst, et al.                                   |   |
|                       | 3                     | us-5916540                                 | 06/29/1999                     | Akehurst, et al.                                   |   |
|                       | 4                     | us-5847128                                 | 12/08/1998                     | Martin, et al.                                     |   |
|                       | 5                     | us-5804592                                 | 09/08/1998                     | Volicer  |   |
|                       | 6                     | us-5736124                                 | 04/07/1998                     | Akehurst, et al.                                   |   |
|                       | 7                     | us-5716638                                 | 02/10/1998                     | Touitou  |   |
|                       | 8                     | us-5635530                                 | 06/03/1997                     | Mechoulam, et al.                                  |   |
|                       | 9                     | us-5540934                                 | 07/30/1996                     | Touitou  |   |
|                       | 10                    | us-5508037                                 | 04/16/1996                     | ElSohly  |   |
|                       | 11                    | us-5508023                                 | 04/16/1996                     | Byron, et al.                                      |   |
|                       | 12                    | us-5502076                                 | 03/26/1996                     | Dixit, et al.                                      |   |
|                       | 13                    | us-5492688                                 | 02/20/1996                     | Byron, et al.                                      |   |
|                       | 14                    | us-5447729                                 | 09/05/1995                     | Belenduik, et al.                                  |   |
|                       | 15                    | us-4933363                                 | 06/12/1990                     | ElSohly  |   |
| XQW                   | 16                    | us-4635651                                 | 01/13/1987                     | Jacobs   |   |
|                       |                       | US-  |                                |  |   |
|                       |                       | US-  |                                |  |   |
|                       |                       | US-  |                                |  |   |
|                       |                       | US-  |                                |  |   |

TECH CENTER 1600/2900

RECEIVED

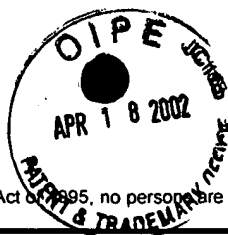
| FOREIGN PATENT DOCUMENTS |                       |                           |   |                                |  |   |
|--------------------------|-----------------------|---------------------------|---|--------------------------------|--|---|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   |   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear |
|                          |                       | Country Code <sup>3</sup> | Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |                                |  |   |
| XQW                      | 17                    | WO                        | 01/13886 A1   | 03/01/2001                     | McPhillips, et al.                                 |   |
|                          | 18                    | WO                        | 00/27359 A1   | 05/18/2000                     | Pilkiewicz   |   |
|                          | 19                    | WO                        | 00/24362 A2   | 05/04/2000                     | Peart, et al.                                      |   |
|                          | 20                    | WO                        | 99/32107 A1   | 07/01/1999                     | Watts, et al.                                      |   |
| XQW                      | 21                    | WO                        | 98/29096 A1   | 07/09/1998                     | Gordon, et al.                                     |   |
|                          |                       |                           |   |                                |  |   |
|                          |                       |                           |   |                                |  |   |
|                          |                       |                           |   |                                |  |   |
|                          |                       |                           |   |                                |  |   |

|                    |                 |                 |        |
|--------------------|-----------------|-----------------|--------|
| Examiner Signature | Lauren D. Wells | Date Considered | 5/9/02 |
|--------------------|-----------------|-----------------|--------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it contains a valid OMB control number.

PTO/SB/08B (10-01)  
Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

## Complete if Known

|                        |            |
|------------------------|------------|
| Application Number     | 09/639,289 |
| Filing Date            | 08/15/2000 |
| First Named Inventor   | M. Dedhiya |
| Group Art Unit         | 1619       |
| Examiner Name          | L. Wells   |
| Attorney Docket Number | 01895284   |

## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|---|----------------|
| XGW ✓              | 22                    | WILLIAMS, ET AL., "Bronchodilator Effect of Delta-Tetrahydrocannabinol Administered By Aerosol to Asthmatic Patients," Thorax, Vol. 31 ( No. 6), p. 720-723, (1976).  |                |
| ✓                  | 23                    | LICHTMAN, ET AL., "Pharmacological Evaluation of Aerosolized Cannabinoids in Mice," European Journal of Pharmacology, Vol. 399 ( No. 2-3), p. 141-149, (2000).  |                |
|                    | 24                    | AULT, "Techniques and Experiments for Organic Chemistry," Waveland Press, Inc. (Prospect Heights, Illinois), p. 44-50, 183-194, (1987).   |                |
|                    | 25                    | "Aerosol Delivery: Stability Data" (February 18, 1998).   |                |
|                    | 26                    | DEDHIYA, ET AL., "Current Concepts For Delivery of D-9 THC: Prospects For Cannabinoid Drug Development," (1998).  |                |
| ✓                  | 27                    | VACHON, ET AL., "Airways Response to Aerosolized Delta-9-Tetrahydrocannabinol: Preliminary Report," The Therapeutic Potential of Marihuana, Plenum Medical Book Company (New York and London), p. 111-121, (1976).  |                |
|                    | 28                    | FRATELLO, "NIH Study Helps the Case For Medical Marijuana," The Sacramento Bee, ( September 5, 1997).   |                |
|                    | 29                    | LEWIS, "Just Say 'Research'," The Scientist, Vol. 12 ( No. 3), p. 1&6, (February 2, 1998).  |                |
|                    | 30                    | LITTLE, "Studies of Stability and Purification of Delta 9-Tetrahydrocannabinol," ( November 1970).  |                |
|                    | 31                    | GARRETT, ET AL., "Physicochemical Properties, Solubility, and Protein Binding of Delta 9-Tetrahydrocannabinol," Journal of Pharmaceuticall Sciences, p. 1056-1064, (1974).  |                |
| XGW ✓              | 32                    | OHLSSON, ET AL., "Plasma Delta-9-Tetrahydrocannabinol Concentrations and Clinical Effects After Oral and Intravenous Administration and Smoking," Clinical Pharmacology and Therapeutics, Vol. 28 ( No. 3), p. 409-416, ( September 1980).                      |                |

Examiner  
Signature

Larry Q. Wells

Date

Considered

5/10/02

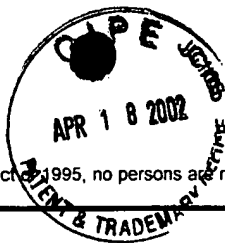
\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

APR 24 2002

RECEIVED



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

PTO/SB/08B (10-01)  
Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+  
RECEIVED  
APR 24 2002  
TECH CENTER 1600/2900

|   |                        |                          |            |
|---|------------------------|--------------------------|------------|
| Substitute for form 1449B/PTO   |                        | <b>Complete if Known</b> |            |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |                        | Application Number       | 09/639,289 |
|   |                        | Filing Date              | 08/15/2000 |
|   |                        | First Named Inventor     | M. Dedhiya |
|   |                        | Group Art Unit           | 1619       |
|   |                        | Examiner Name            | L. Wells   |
| Sheet 2 of 2  | Attorney Docket Number | 01895284                 |            |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS |                          |   |                |
|--|--------------------------|---|----------------|
| Examiner<br>Initials*                              | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
| XQW  | 33                       | PEREZ-REYES, ET AL., "Pharmacology of Orally Administered Delta-9-Tetrahydrocannabinol," Clinical Pharmacology and Therapeutics, Vol. 14 ( No. 1), p. 48-55, (1973).  |                |
| XQW  | 34                       | TASHKIN, ET AL., "Bronchial Effects of Aerosolized Delta-9-Tetrahydrocannabinol in Healthy and Asthmatic Subjects," American Review of Respiratory Disease, p. 57-65, (1977).   |                |
|  |                          |   |                |
|  |                          |   |                |
|  |                          |   |                |
|  |                          |   |                |
|  |                          |   |                |
|  |                          |   |                |
|  |                          |   |                |
|  |                          |   |                |
|  |                          |   |                |
|  |                          |   |                |
|  |                          |   |                |
|  |                          |   |                |

|                       |                       |                    |         |
|-----------------------|-----------------------|--------------------|---------|
| Examiner<br>Signature | <i>Ramon O. Wells</i> | Date<br>Considered | 5/10/02 |
|-----------------------|-----------------------|--------------------|---------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.